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Charles W. Ashbrook
Assistant General Counsel, Pharmaceutical Patents
WARNER-LAMBERT COMPANY
Parke-Davis Pharmaceutical Research Division
2800 Plymouth Road/Ann Arbor MI 48105

Re: Patent Term Extension
Application for
U.S. Patent No. 4,935,507

JP

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,935,507, which claims the human drug product OMNICEF® Oral Suspension (cefdinir), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,213 days, as correctly stated in the application for patent term extension.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,213 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 20, 1999 (64 Fed. Reg. 27579).¹ Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,406 - 18) + 339 \\ &= 1,533 \text{ days}\end{aligned}$$

Since the regulatory review period began June 1, 1990, before the patent issued (June 19, 1990), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From June 1, 1990 to June 19, 1990 is 18 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,533 days, would extend the patent from August 8, 2008 (35 U.S.C. § 154) to October 19, 2012, which is beyond the 14-year limit (the approval date is December 4, 1997, thus the 14 year limit is December 4, 2011). The period of extension is thus limited to December 4, 2011, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, August 8, 2008, to and including December 4, 2011, or 1,213 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

¹The regulatory review period for OMNICEF® Tablets published in the Federal Register on May 20, 1999 (64 Fed. Reg. 27578) is a different regulatory review period.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 4,935,507
Granted: June 19, 1990
Original Expiration Date²: August 8, 2008
Applicant: Takao Takaya, et al.
Owner of Record: Fujisawa Pharmaceutical Co., Ltd.
Title: Crystalline 7-(2-(2-Aminothiazol-4-Yl)-2-Hydroxyiminoacetamido)-3-Vinyl-3-Cephem-4-Carboxylic Acid (Syn Isomer)
Classification: 540/222
Product Trade Name: OMNICEF® Oral Suspension (cefdinir)
Term Extended: 1,213 days
Expiration Date of Extension: December 4, 2011

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231
By FAX: (703) 308-6916 or (703)872-9411
Attn: Special Program Law Office
By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned
at (703) 306-3159.

Karin L. Tyson
Karin L. Tyson
Senior Legal Advisor, Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read RE: OMNICEF® Oral Suspension (cefdinir)
Acting Director Regulatory Policy Staff, CDER FDA Docket No.: 98E-0840
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

²Subject to the provisions of 35 U.S.C. § 41(b).